

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Young et al.

Docket No.: PF383D1

Application No.: Not Yet Assigned

Group Art Unit: N/A

Filed: Herewith

Examiner: Not Yet Assigned

For: Heregulin-like Factor

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 to inform the Patent and Trademark Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of a claim of the subject application, Attorney for Applicants hereby directs the Examiner's attention to references A-U listed on the attached Form SB/08.

Copies of references A-U were submitted by Applicants or cited by the Examiner in connection with United States Patent Application No. 09/097,681, filed on June 16, 1998, to which the instant application claims priority under 35 U.S.C. § 120. Pursuant to 37 C.F.R. § 1.98(d), the Examiner is directed to the file of United States Patent Application No. 09/097,681 for copies of references A-U.

The listed references are presented so that the Patent and Trademark Office can determine any materiality thereof to the claimed invention. See 37 C.F.R. § 1.104(a) concerning the Examiner's duty to consider and use any such information. Applicants respectfully request that the Examiner make the listed references of record in the file history of the application, and consider the information contained therein during the prosecution of this application.

Identification of the listed references is not to be construed an admission of any individual associated with the filing or prosecution of the subject application that such references are available as "prior art" against the subject application. Furthermore, Applicants

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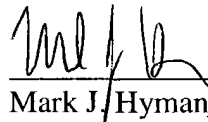
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do not waive any rights to take appropriate action to establish patentability over any of the listed documents should they be applied as references against the claims of the subject application.

Pursuant to 37 C.F.R. § 1.97(b), this Information Disclosure Statement is being filed before the mailing of a first Office Action on the merits. Accordingly, no fee is believed due. However, should the Patent Office determine otherwise, please charge the required fee to our Deposit Account No. 08-3425.

Respectfully submitted,

Dated: July 1, 2003

  
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|  |   |    |   | Application Number       | Not Yet Assigned      |
|  |   |    |   | Filing Date              | Concurrently Herewith |
|  |   |    |   | First Named Inventor     | Paul E. Young         |
|  |   |    |   | Art Unit                 | N/A                   |
|  |   |    |   | Examiner Name            | Not Yet Assigned      |
| Sheet  | 1 | of | 3 | Attorney Docket Number   | PF383D1               |

| U.S. PATENT DOCUMENTS |                          |  |                                |  |   |
|-----------------------|--------------------------|--|--------------------------------|--|---|
| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|                       |                          | Number-Kind Code <sup>2</sup> (if known) |                                |  |   |
|                       | A                        | US-6,096,871                             | 08-01-2000                     | Presta et al.                                      |   |
|                       | B                        | US-6,121,415-B1                          | 09-19-2000                     | Godowski et al.                                    |   |
|                       | C                        | US-6,252,051-B1                          | 06-26-2001                     | Godowski et al.                                    |   |

| FOREIGN PATENT DOCUMENTS |                          |   |                                   |  |   |                |
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| Examiner<br>Initials*    | Cite<br>No. <sup>1</sup> | Foreign Patent Document   | Publication<br>Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear | T <sup>6</sup> |
|                          |                          | Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known) |                                   |  |   |                |
|                          | D                        | WO-99/02681-A9  | 01-21-1999                        | Genentech, Inc.                                    |   |                |

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|   |   |    |   | Art Unit                 | N/A                   |
|   |   |    |   | Examiner Name            | Not Yet Assigned      |
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| NON PATENT LITERATURE DOCUMENTS |                       |   |                |  |
|---------------------------------|-----------------------|---|----------------|--|
| Examiner Initials               | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |  |
|                                 | E                     | LEWIS et al., "Growth Regulation of Human Breast and Ovarian Tumor Cells by Heregulin: Evidence for the Requirement of ErbB2 as a Critical Component in Mediating Heregulin Responsiveness," <i>Cancer Res.</i> , 56:1457-1465 (Mar. 1996)                      |                |  |
|                                 | F                     | ZHANG et al., "Neuregulin-3 (NRG3): A novel neural tissue-enriched protein that binds and activates ErbB4," <i>PNAS USA</i> , 94:9562-9567 (Sep. 1997)  |                |  |
|                                 | G                     | HOLMES et al., "Identification of Heregulin, a Specific Activator of p185erbB2," <i>Science</i> , 256:1205-1210 (May 22, 1992)  |                |  |
|                                 | H                     | GEORGE et al., "Macromolecular Sequencing and Synthesis: Selected Methods and Application," Schlesinger, D.H. (eds.), Alan R. Liss, Inc., New York, NY, pp. 127-149 (1988)  |                |  |
|                                 | I                     | WILSON, R.K., "The WashU-Merck EST Project," GenBank Accession No. H50042 (Sep. 18, 1995)   |                |  |
|                                 | J                     | WILSON, R.K., "The WashU-Merck EST Project," GenBank Accession No. H49100 (Sep. 18, 1995)   |                |  |
|                                 | K                     | WILSON, R.K., "The WashU-Merck EST Project," GenBank Accessoin No. H23651 (Jul. 6, 1995)  |                |  |
|                                 | L                     | CULOUSCOU et al., "Characterization of a breast cancer cell differentiation factor that specifically activates the HER4/P180ERB4 receptor," <i>J. Biol. Chem.</i> , 268(25):18407-18410 (1993)  |                |  |
|                                 | M                     | GARRAWAY et al., "Neuregulin-2, a new ligand of Erb3/Erb4-receptor tyrosine kinase," <i>Nature</i> , 387:512-516 (1997)   |                |  |
|                                 | N                     | GASSMANN et al. "Aberrant neural and cardiac development in mice lacking the Erb4 neuregulin receptor," <i>Nature</i> , 378(6555):390-394 (1995)  |                |  |
|                                 | O                     | HIJAZI et al. "NRG-3 in human breast cancers: Activation of multiple erbB family proteins," <i>Int'l. J. Oncology</i> , 13(5):1061-1067 (1998)  |                |  |
|                                 | P                     | LAVERRIERE et al. "GATA-4/5/6, a subfamily of three transcription factors transcribed in developing heart and gut," <i>J. Biol. Chem.</i> , 269(37):23177-23184 (1994)  |                |  |
|                                 | Q                     | PLUMB et al., "Human DNA sequence from clone RP1-185K11," Database EMBL 'Online' Accession No. AL136085 (Jan. 7, 2000)  |                |  |
|                                 | R                     | BOWIE et al., "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions," <i>Science</i> , 247:1306-1310 (1990)  |                |  |
|                                 | S                     | LAZAR et al., "Transforming Growth Factor Alpha: Mutation of Aspartic Acid 47 and Leuine 48 Results in Different Biological Activities," <i>Molec. and Cell. Biol.</i> , 8:1247-1252 (1988)   |                |  |

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| Sheet  | 3 | of | 3 | Attorney Docket Number   | PF383D1               |

|  |   |   |  |
|--|---|---|--|
|  | T | BURGESS et al., "Possible Dissociation of the Heparin-binding and Mitogenic Activities of Heparin-binding Growth Factor-1 from Its Receptor-binding Activities by Site-directed Mutagenesis of a Single Lysine Residue," <i>J. Cell. Biol.</i> , 111:2129-2138 (1990) |  |
|  | U | BORK, P., "Powers and the pitfalls in sequence analysis," <i>Genome Res.</i> , 10:398-400 (2000)  |  |

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